



Virginia
Regulatory
Town Hall

Proposed Regulation Agency Background Document

Agency Name:	DMHMRSAS
VAC Chapter Number:	12 VAC 35-110-10 et seq.
Regulation Title:	Rules and Regulations to Assure the Rights of Residents of Facilities Operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services
Action Title:	Repeal
Date:	2/24/2000

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form, Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This regulation became effective July 1, 1983 and was designed to protect the rights of individuals receiving mental health, mental retardation and substance abuse services in facilities operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS). Through this regulation, and to the extent that it is within the reasonable capabilities of the facility, each resident is assured adequate care consistent with sound therapeutic treatment. The regulation was developed to protect the rights of individuals with respect to the assurance of legal rights; evaluation, treatment, and discharge; treatment under the least restrictive conditions; participation in treatment decisions, research, and work activities; disclosure of confidential information; and the rights and remedies for violations.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

The regulation to be repealed was promulgated pursuant to §37.1-84.1 of the Code of Virginia (1950) as amended and applicable sections of Chapter 1.1:1, Title 9, Code of Virginia (1950) as amended, known as the Administrative Process Act. This regulation was necessary to fulfill the department’s legislative mandate pursuant to §37.1-84.1 to promulgate regulations delineating the rights of patients and residents with respect to: nutritionally adequate diet, safe and sanitary housing, participation in non-therapeutic labor, attendance or nonattendance at religious services, participation in treatment decision-making, including due process procedures to be followed when a patient or resident may be unable to make an informed decision, use of telephones, availability of suitable clothing and possession of money and valuables, and related matters. The Code also required that such regulation be applicable to all hospitals and other programs and facilities operated, by the DMHMRSAS .

The Office of the Attorney General certified that the Department of Mental Health, Mental Retardation and Substance Abuse Services has the statutory authority to promulgate the regulation and that the regulation comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

This regulation was designed to protect the legal and human rights of all residents of facilities operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services. This regulation is to be replaced by a regulation which covers all facilities and programs, operated, licensed and funded by DMHMRSAS. The current regulation was promulgated in 1983 and is being repealed for the following reasons:

? The regulation is not consistent for all facilities and programs licensed, funded and operated by the department,

- ? The regulation does not incorporate changes in the law,
- ? The regulation is not clear and specific on the rights of consumers and families,
- ? The regulation does not clearly state the responsibilities of providers,
- ? The regulation does not clearly state the review and resolution process, and
- ? The regulation does not provide timeframes for each stage of review.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

This regulation has not been revised since 1983. The current regulation is being revised and reformatted to facilitate clarity and consistency of the rights of individuals across community and facility programs, clearly identify provider duties and responsibilities, and describe any exceptions to each regulation.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

Since 1983, numerous problems have been identified with the existing regulation. These problems include:

- ? Inconsistencies between a regulation for facilities operated by the DMHMRSAS, the regulation for licensed inpatient programs and the regulation for community programs resulting in confusion for consumers, families and providers;
- ? Changes in the law are not reflected in the existing regulation;
- ? Changes in practice are not reflected in the existing regulation;

- ? Time frames for the review/resolution of complaints are not specified in the existing regulation, resulting in protracted case reviews;
- ? Multiple regulations are imposed on public and private programs and facilities that provide inpatient and outpatient services;
- ? Confusion for consumers and families often results when an individual moves from one type of program to another (e.g. inpatient to community program) each with a separate set of human rights regulations; and
- ? Time frames for the review and resolution of each complaint are not included in the regulation.

In 1992, the State Board of Mental Health, Mental Retardation and Substance Abuse Services adopted a resolution to consolidate the three existing regulations into a single regulation applicable to all facilities and programs operated, funded or licensed by the DMHMRSAS. A 1996 comprehensive review of the existing human rights regulations and the public comment received during that review demonstrated extensive public support for a single, consolidated regulation. There has been no show of support for maintaining the current regulations.

There are no disadvantages to the public or Commonwealth by the repeal of this regulation and replacement with a consolidated regulation.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

There are no projected new or additional costs associated with the repeal of this regulation and its replacement with a new consolidated regulation. The agencies to be affected by the repeal of the regulation include the 15 DMHMRSAS operated mental health and mental retardation facilities.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

The Department of Mental Health Mental Retardation and Substance Abuse Services proposes to repeal the current regulation and replace it with a regulation which consolidates and revises three separate existing regulations that were promulgated by the department to protect the legal and human rights of consumers of public and private facilities and programs operated, funded and licensed by the department.

Specific changes to the proposed regulation include:

? Clearly defining the composition, role, and function of the internal human rights system, the local human rights committees, and the State Human Rights Committee. A 1999 revision to the Code of Virginia requires that one-third of the appointments made to the state or local human rights committees be consumers or family members of consumers with at least two consumers who are receiving services on each committee.

? Requiring monitoring and evaluation of provider compliance with the regulation. A 1999 revision to the Code of Virginia requires that there be periodic reviews of human rights compliance. Licensing by DMHMRSAS will be contingent upon human rights compliance

? Establishing procedures for enforcement and sanctions for violations of human rights. A 1999 revision to the Code of Virginia allows for sanctioning of those providers who fail to comply with human rights regulations.

? Establishing procedures and time frames for the resolution process in the internal human rights system.

? Establishing procedures for the application, review and approval of variances from specific standards or procedures in the regulation.

? Establishing requirements for reporting, data submission and the release of data to the public. A 1999 revision to the Code of Virginia requires that all programs and facilities operated, funded and licensed report information on abuse and neglect, deaths and serious injury, instances of seclusion and restraint, and other information on human rights activities.

? Establishes a prohibition on employees of programs and facilities operated, funded, or licensed by the department from serving as the authorized representative of a consumer in the program.

? Changing the format of the regulation to clarify individual rights, provider responsibilities, and exceptions.

? Simplifying the language of the regulation such that consumer, families and providers may understand the regulation.

? Updating the standards and terminology to reflect current practice.

Alternatives

Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

Several alternatives have been considered in proposing the repeal of the this regulation to protect the legal and human rights of consumers of services in facilities operated by DMHMRSAS.

These alternatives include:

1. No regulation. This alternative was rejected. Repealing the existing human rights regulation without replacment is in violation of §37.1-84.1 of the Code of Virginia, which requires the State Mental Health, Mental Retardation and Substance Abuse Services Board to promulgate regulations delineating the rights of patients and residents in all hospitals and other facilities and programs operated, funded or licensed by the Department of Mental Health, Mental Retardation and Substance Abuse Services.
2. No change to existing regulations. This alternative was rejected. The existing regulation have not been revised since 1983. Changes are needed to address consumer and family concerns, inconsistencies in regulations for inpatient programs and community programs, and changes in current practice. This alternative is also not viable because of statutory changes in 1999.
3. Update the existing regulation for facilities operated by DMHMRSAS. This alternative was rejected. While the existing regulations provides some assurances that the legal and human rights of consumers are protected, they are confusing to consumers and families and they create an unnecessary burden for public and private providers who may be required to adhere to multiple regulations. In 1992, the State Board of Mental Health, Mental Retardation and Substance Abuse Services adopted a resolution to consolidate the three existing regulations into a single regulation applicable to all facilities and programs operated, funded or licensed by the department. A 1996 comprehensive review of the existing human rights regulations and the public comment received during that review demonstrated extensive public support for a single, consolidated regulation. There has been no show of support for maintaining the current regulations.
4. Repeal the three existing sets of human rights regulations and promulgate a single consolidated regulation. This alternative was chosen. Consolidation of the three human rights regulations into a single regulation will establish a single set of standards that protect the rights of persons with mental disabilities who receive services in facilities and programs operated, funded and licensed by the department regardless of the setting. This alternative is widely supported in the advocacy community and by public and private providers of mental health, mental retardation and substance abuse services.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

There were no comments made during the NOIRA comment period.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The Department of Mental Health and Mental Retardation has determined that the language of the current regulation lacks clarity and specificity. This determination is based on the comments of consumers and advocacy groups. Specific areas lacking in clarity and specificity include: definitions, provider responsibilities, exceptions to regulations, and specificity as to the procedures to follow at each level of appeal.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

The current regulation has not been reviewed or revised since 1983. In 1992 and again following the periodic review of all three sets of the existing human rights regulations (12 VAC 35-110, 12 VAC 35-120, and 12 VAC 35-130 in 1996, the State Mental Health, Mental Retardation and Substance Abuse Services Board recommended that these regulations be consolidated into a single regulation. Following this recommendation, the DMHMRSAS convened an advisory committee to assist in drafting the consolidated regulations. The DMHMRSAS initiated the process of repealing the three sets of existing regulations and replacing them with a new consolidated human rights regulation that would establish a single standard for all programs operated, funded, and licensed by the Department.

A new proposed regulation was drafted and proceeded through the regulatory process in late 1997 and 1998. Because of the substantive nature of comments received on the proposed regulation during the public comment period and the likelihood of statutory changes to implement the recommendations of then HJR 240 (now HJR 225) Joint Subcommittee Studying the Future Delivery of Mental Health, Mental Retardation and Substance Abuse Services, the Department decided in late 1998 to withdraw this regulation from the regulatory process and to begin the regulatory process again with a new consolidated regulation. The regulatory process is underway (12 VAC 35-115).

The Department of Mental Health, Mental Retardation and Substance Abuse Services will review and evaluate the need for amendments or revision to a consolidated revised regulation no later than July of 2003 and every three years thereafter.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

This regulation explains the human rights of the individual as a recipient of services in a facility operated by the Department. This regulation provides some assurance to family members that the human rights of their loved ones who are receiving mental health, mental retardation, and substance abuse services are protected and that there are procedural safeguards in place to address violations to these rights. Such assurance is essential to the peace of mind of many families who have entrusted the care and well-being on their loved one to a service provider.

This regulation has no impact on the institution of the family and family stability.

1. This regulation does not erode the authority and rights of parents in the education, nurturing and supervision of their children. It clearly speaks to the responsibilities of providers to obtain the consent of at least one parent of a minor before any treatment, including medical treatment, begins. It also provides for an individual's next of kin to be designated as a legally authorized representative when an individual lacks the capacity to give consent for any treatment.
2. This regulation does not discourage the economic self-sufficiency, self-pride and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents.
3. This regulation has no effect on the marital commitment; and

This regulation has no effect on family income.